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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/369,883	08/09/1999	JOEL CROUZET	038806.0448	7384

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1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER
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KETTER, JAMES S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER
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011104

DATE MAILED:

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Commissioner for Patents

--See attached--

## Office Action Summary

Application No.

09/369,883

Applicant(s)

CROUZET ET AL.

Examiner

James S. Ketter

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20, 22-25 and 27-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-20, 22-24, 27-44 and 48-51 is/are rejected.
- 7) ☒ Claim(s) 7-9, 25 and 45-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 August 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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With respect to the restriction requirement mailed 17 November 2000, a review of said requirement, made by the previous Examiner of record, shows that there was considerable confusion by him regarding the different elements of the claimed or recited compositions. Claims clearly reading on the elected species were set forth as distinct, for no clear reason. After no art was found with respect to the elected species, the search was expanded to the other embodiments. All pending claims, and all species therein, are hereby **rejoined**, and an examination thereof on the merits follows.

Claims 7-9, 25 and 45-47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 11-17, 23, 27, 29, 31, 35-37, 42-44 and 49-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Heidrun et al. (A, newly cited).

Heidrun et al. teaches, e.g., at the paragraph bridging columns 4-6, a “gene delivery system” which uses a lipid encapsulated DNA or cationic lipid/DNA complex (lines 3-4), and

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then a delivery-enhancing agent including nonylphenoxypolyoxyethylene (line 38 of column 5) and polyoxyethylene ethers (line 40 of column 5). Said delivery-enhancing agent corresponds to the recited non-ionic surface-active agent. At the top of column 6, the concentration ranges of said agent are set forth as 1% to 50%. With respect to claim 29, since the recited feature of "chemically modified" is not more narrowly defined, it would be understood that any cutting or ligation of a DNA, e.g., a plasmid, would read on this limitation. With respect to the limitation that the sizes of the particles are less than about 160 nm, it is clear that this would inherently result from use of nonylphenoxypolyoxyethylene, which is an embodiment disclosed in the instant specification.

Claims 1-6, 10, 12-20, 22-24, 27, 29, 31, 32, 35-44, 48, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Tam et al. (B, newly cited).

Tam et al. teaches, e.g., at column 7, lines 25-67, AAV vectors complexed with cationic lipids, e.g., DOTMA, LIPOFECTIN, LIPOFECTAMINE, and also a detergent solution, e.g., BRIJ (lines 58 and 59). The charge ratios employed are set forth at the top of column 8, ranging from 1 to 20, and the detergent concentrations set forth at the bottom of column 7. With respect to claim 29, since the recited feature of "chemically modified" is not more narrowly defined, it would be understood that any cutting or ligation of a DNA, e.g., a plasmid, would read on this limitation. At column 8, lines 14-38, it is taught to use non-cationic lipids in addition to the other components, e.g., DOPE (line 29). Also at column 8, lines 14-38, it is taught that cerebroside and sphingomyelin may be employed. At column 7, line 45, the use of DOGS as the cationic lipid is taught.

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Claims 1-6, 10, 12-20, 22-24, 27, 29, 31-44, 48, 50 and 51 are rejected under 35 U.S.C. 102(e) as being anticipated by Wheeler et al. (C, newly cited).

Wheeler et al. teaches, e.g., at column 8, lines 18-34, cationic lipids for coating nucleic acids, e.g., LIPOFECTIN, DOTMA, LIPOFECTAMINE, and also a detergent solution, e.g., BRIJ (line 42). The charge ratios employed are set forth at the bottom of column 8, ranging from 1 to 20, and the detergent concentrations set forth in the preceding paragraph of column 8. With respect to claim 29, since the recited feature of "chemically modified" is not more narrowly defined, it would be understood that any cutting or ligation of a DNA, e.g., a plasmid, would read on this limitation. At column 9, first paragraph, it is taught to use non-cationic lipids in addition to the other components, e.g., DOPE (line 16). Also at column 9, first paragraph, it is taught that cerebroside and sphingomyelin may be employed. At column 8, line 33, the use of DOGS as the cationic lipid is taught. At column 7, lines 34-41, use of RNA, particularly antisense, as the nucleic acid is taught. At column 12, second full paragraph, the use of targeting moieties, including antibodies, attached to the plasmid-lipid particles, is taught.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155 (or to (571) 273-0770 after 1/13/2004). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be

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retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169 (or (571) 272-0770 after 1/13/2004). The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk  
January 11, 2004



JAMES KETTER  
PRIMARY EXAMINER